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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,372	07/24/2003	Harrihar A. Pershadsingh	421842000400	2447

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EXAMINER

WEDDINGTON, KEVIN E

ART UNIT PAPER NUMBER

1614

DATE MAILED: 01/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/627,372	Applicant(s) PERSHADSINGH, HARRIHAR A.	
	Examiner Kevin E. Weddington	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-12,14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-12,14 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10-26-05</u> . | 6) <input type="checkbox"/> Other: _____ |

The finality of the Office action dated June 29, 2005 is vacated so that rejections can be made.

Claims 1-7, 9-12, 14 and 15 are presented for examination.

Applicant's amendment filed August 26, 2005; the information disclosure statement filed October 26, 2005; and terminal disclaimer filed November 28, 2005 have been received and entered.

Accordingly, the rejection made under obviousness-type double patenting as set forth in the Office action date June 29, 2005 is hereby withdrawn because a terminal disclaimer was filed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Asmar, R et al., "Effects of Telmisartan on Arterial Compliance and Endothelial Function in Type 2 Diabetes Patients with Essential Hypertension", American Journal of Hypertension 14(4): 114A, 2001, abstract P-254 of PTO-1449.

Asmar et al. teach the administration of telmisartan to type 2 diabetes patient with essential hypertension, condition associated with type 2 diabetes (see the abstract). The reference also teaches the dosage of telmisartan administered to the patients was 40 mg which falls within applicant's dosage range disclosed in claim 12.

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As for the mechanism in which the telmisartan achieves, at least partially activate peroxisome proliferation activated receptors (PPARs) and at least partially inhibit, antagonize or block an activity of angiotensin II type 1 receptors, a product of identical chemical composition cannot have mutually exclusive properties. If the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present (See In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)). Clearly, the cited reference teaches the telmisartan being administered type 2 diabetes patient with hypertension would inherently treat metabolic syndrome since hypertension is a symptom associated with metabolic syndrome.

Claims 1-7, 9, 11 and 12 are not allowed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asmar, R et al., "Effects of Telmisartan on Arterial Compliance and Endothelial Function in Type 2 Diabetes Patients with Essential Hypertension", American Journal of Hypertension 14(4): 114A, 2001, abstract P-254 of PTO-1449.

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Asmar et al. were discussed above for the administration of telmisartan to type 2 diabetes patients with essential hypertension.

The instant invention differs from the cited reference in the cited reference does not teach the telmisartan is formulated for topical administration. However, one skilled in art would have assumed the topical administration of telmisartan is a well-known mode of administration in the pharmaceutical art.

The instant invention differs from the cited reference in that the cited reference does not teach the total effective daily orally administered dose of telmisartan to a human child, adolescent or adult as set forth in claims 14 and 15 are well-known in the pharmaceutical art. The various dose ranges of claim 14 is obvious since the body sizes of the human child, adolescent and adult are different thus various doses in need for each group. For example, a human child will need a smaller dose than an adolescent.


Claims 10, 14 and 15 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington
December 28, 2005